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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,989	11/06/2001	Jaime Simon	61350A	5337

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THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,989

Applicant(s)

SIMON ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 13 is objected to because of the following informalities: the word "is" between "coating" and "selected" in line 1 is missing. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,470,975.

The patent provides a method for removing excess water from the body, which is useful in the treatment of edema, water intoxication in renal failure and congestive heart failure, comprising administering hydrophilic, crosslinked polysaccharides to the intestinal tract (See abstract and col. 3, lines 1-64). The patent teaches that preferred crosslinked polysaccharides are copolymerization products in the form of grains, exhibiting a water regain (expressing capacity of swelling) in the range of 1-85 grams of water or more (See col. 4, lines 34-55). In the examples provided, the sephadex is administered orally (See Example 1).

The method and composition disclosed by the patent meet the limitations of claims 1 and 16 of the instant application, as they contemplate methods for removing fluid from the intestinal tract

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or treating fluid overload states, comprising delivering a water-absorbing polymer to the intestinal tract. Thus, the patent anticipates the claimed invention.

4. Claims 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0077956. The patent discloses microcapsules obtained by incorporating a water-swellaable polymer into the core material and incorporating an enteric polymeric material in the coating, and capable of releasing the core material in the intestinal tract (See p. 2, lines 3-24). The patent includes phthalic acid esters of hydroxyalkyl alkylcellulose or cellulose acetate among the enteric polymers used in the invention (See p. 4, lines 4-19). The patent teaches that the water-swellaable polymer shows at least 1.2 times increase in weight when immersed in water and includes polysaccharides, copolymers of divinylbenzene and acrylic acid, and crosslinked polyacrylic acid among the water-swellaable polymers encompassed by the invention (See p. 5, line 22 to p. 6, line 9). The patent teaches that the core comprising the water-swellaable polymer is in the form of granule.

The compositions disclosed by the patent meet the limitations of claims 19-27 of the instant application, as they contemplate compositions comprising enterically coated water-absorbing polymers. Thus, the patent anticipates the claimed invention.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Polycarbophil.

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The product description discloses a polyacrylic resin capable of absorbing up to 60 times its weight in water, used to treat diarrhea and constipation and working in the small and large intestines.

The composition and methods of using said composition disclosed by the product description meet the limitations of claims 1 and 16 of the instant application, as they contemplate methods for removing fluid from the intestinal tract or treating fluid overload states, comprising delivering a water-absorbing polymer to the intestinal tract. Thus, the product description anticipates the claimed invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts (WO 95/35100) in view of Berger et al. (U.S. Patent 4,470,975) or Imondi et al. (U.S. Patent 4,143,130).

Watts provides a drug delivery composition for delivering a drug to the colon, said composition comprising a coated capsule (See p. 3, lines 25-29). Watts et al. teaches that the coating can be made of enteric coatings (See p. 5, line 20 to p. 6, line 22) and the drug can be used to treat local conditions, such as constipation, and colon diseases (See p. 8, lines 14-23).

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Thus, Watts provides an enterically coated capsule comprising a drug for the treatment of colon diseases. Watts et al. is deficient in the fact, that it does not specifically mention water-swellaable polymers among the active agents, which may be included in the compositions and are effective in the treatment of colon diseases.

Berger et al. provides a method for removing excess water from the body, which is useful in the treatment of edema, water intoxication in renal failure and congestive heart failure, comprising administering hydrophilic, crosslinked polysaccharides to the gastrointestinal tract (See abstract and col. 3, lines 1-64). The patent teaches that preferred crosslinked polysaccharides are copolymerization products in the form of grains, exhibiting a water regain (expressing capacity of swelling) in the range of 1-85 grams of water or more (See col. 4, lines 34-55). In the examples provided, the sephadex is administered orally (See Example 1).

Imondi et al. provides water soluble carboxylic acid polymers promoting phosphate absorption and having a swelling index of 10-1500, and teaches that the compositions of the invention may be formulated in enterically coated capsules (See col. 1, line 1 to col. 4, line 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the enterically coated capsules disclosed by Watts, by including a water swellaable polymer as active agent, to obtain compositions, which are effective in removing excess water from the intestinal tract, and device methods of treatment using said compositions. The expected result would have been a successful composition and successful methods of

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treatment. Because of the teachings of Watts, that coated capsules of the invention may comprise drugs, which are effective in the local treatment of colon diseases, and the teachings of Berger et al. and Imondi et al., that water-swellable polymers are effective in the treatment of water excess and kidney diseases, one of ordinary skill in the art would have a reasonable expectation that the methods and compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

SDH

February 3, 2003

Thurman K. Page
THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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